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| 10/557,923 | 03/10/2006 | Gianfranco De Paoli Ambrosi | 5759 | 8082 |
| 26936 | 7590 | 01/20/2011 | EXAMINER | |
| SHOEMAKER AND MATTARE, LTD | | | VENKAT, JYOTHSNA A | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/557,923 | Applicant(s) DE PAOLI AMBROSI, GIANFRANCO |
| | Examiner JYOTHSNA A. VENKAT | Art Unit 1619 |

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 November 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21-23,25-31,41 and 42 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21-23, 25-31 and 41-42 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Receipt is acknowledged of remarks and declaration under 37 C.F.R. 1.132 filed on 11/4/10.

Status of claims

Claims 1-20, 24 and 32-40 are cancelled. Claims 21-23, 25-31 and 41-42 are pending in the application. Election is without traverse drawn to the combination of trifluoro acetic acid (keratolytic agent) and dimethyl isosorbide.

Claim Rejections - 35 USC § 103

Claims 21-23, 25-28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 5,166,176 ('176) and 4,082,881 ('881).

Claim analysis

Claims are drawn to composition. Preamble and intended use does not carry any patentable weight as the claims are drawn to compositions and not to method of use.

Patent '176 teaches compositions for healing damaged skin comprising claimed trichloroacetic acid (abstract). Patent at col.1, ll 32-34 teaches trichloroacetic acid peel for damaged skin. Patent at col.3, ll 5-8 for the amount of trichloroacetic acid which is from 10- about 50 % and this meets the limitations of claims 22-23 for the amount of trichloroacetic acid. Patent under claim 2 is claiming trichloroacetic acid and under claim 11 is claiming the amount of trichloroacetic acid. Patent '176 also teaches using surfactants (also known as emulsifiers belonging to excipients of claims 27- 28) at col.3, line 34 through col.4, line 16. Patent under claim 10 is claiming surfactant and under claim 11 is claiming the amount of surfactant. Patent at col.4, ll 61-65 teaches glycerin and at col.5, ll 1-10 teaches glycols drawn to claimed solvents

(claims 27-28). Claim 20 of patent is to water (solvent of claims 27-28). Patent at col.5, ll 14-17 teaches adding antioxidants so that oxidative destruction of the composition is prevented. Claim 21 of patent is to antioxidant and claim 22 of patent is to preservatives (claims 27-28 under excipients). The difference between the patent and instant application is patent does not teach dimethyl isosorbide.

Patent '881 teaches topical and other pharmaceutical formulations containing isosorbide carrier. Patent '881 under abstract teaches isosorbide as solvent and at col.2, ll 14 teaches claimed dimethyl isosorbide and at col.2, ll 17-21 teaches the amount which is 0.5-95%. Both the patents teach amount of keratolytic agent and dimethyl isosorbide which meet limitations of claims 22-23 and thus meet the ratio range claimed in claim 21 and claim 41.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare peel compositions by using trichloroacetic acid which is taught and claimed by patent '176 and add solvent dimethyl isosorbide taught by patent '881 with the reasonable amount of success that the dimethyl isosorbide when used as vehicle is capable of solubilizing the keratolytic agent trichloroacetic acid and the solvent being dermatologically beneficial, stable and pharmaceutically acceptable for topical formulations. This is *prima facie* case of obviousness.

Response to Arguments

Applicant's arguments filed 11/4/10 have been fully considered but they are not persuasive.

Applicant argue that patent '881 discloses topical and other pharmaceutical formulations containing isosorbide as the carrier and teaches steroids as the active principal ingredient and no

reference is made to chemical peeling and thus the teachings of patents '881 and '176 do not make it obvious to combine dimethyl isosorbide and keratolytic agent in chemical peeling.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Patent 176 at col.1, ll 32-34 teaches trichloroacetic acid peel for damaged skin and patent '881 teaches dimethyl isosorbide as the carrier and therefore one of ordinary skill in the art would have reasonable expectation of success that the dimethyl isosorbide when used as vehicle is capable of solubilizing the keratolytic agent trichloroacetic acid and the solvent being dermatologically beneficial, stable and pharmaceutically acceptable for topical formulations.

Applicant is notified that the claims are obvious over the combination of patents '176 and '881 and not over the combination of '881 and '176.

Additionally instant claims are drawn to "compositions" having two ingredients isosorbide and trifluoro acetic acid as the keratolytic agent and not drawn to method of chemical peeling using dimethyl isosorbide and trifluoro acetic acid as the keratolytic agent.

Applicant argue regarding secondary reference, which is patent '881 and argue that even though patent '881 teaches dimethyl isosorbide as the solvent and is stable and pharmaceutically

acceptable for topical formulations, there is nothing in the prior art suggesting that an ameliorated peeling effect would result from a combination of a keratolytic agent and dimethyl isosorbide, to achieve the purposes of limiting, on one hand, the erythematogenous effect of the peeling composition and, and the other hand, allowing a lower content of the keratolytic agent to be included within the composition.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Response to Amendment

The declaration under 37 CFR 1.132 filed 11/4/10 is insufficient to overcome the rejection of claims 21-23, 25-28 and 41 based upon the combination of U. S. Patent 5,166,176 ('176) and 4,082,881 ('881) as set forth in the last Office action because:

1. The declaration showed results for 50% pyruvic acid and dimethyl isosorbide combination. The elected species and art applied is for “trifluoro acetic acid”. There is no test data for this keratolytic agent alone and the combination of trifluoro acetic acid and isosorbide.

2. The declaration showed results for 50% glycolic acid and dimethyl isosorbide combination. The elected species and art applied is for “trifluoro acetic acid”. There is no test data for this keratolytic agent alone and the combination of trifluoro acetic acid and isosorbide

3. What is the percentage weight of isosorbide tested in the declaration?

Therefore 103 rejection is deemed proper.

Claims 29-31 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 5,166,176 ('176) and 4,082,881 ('881) as applied to claims 21-23, 25-28 and 41 above, and further in view of WO 94/05301 ('301).

The patents cited above do not teach claimed dimethyl sulfone. However WO '301 teaches dermatitis compositions using salicylic acid and dimethyl sulfone. Salicylic acid is also a keratolytic agent. Thus WO '3-1 teaches the combination of keratolytic agent and dimethyl sulfone. See the abstract. See page 7 under table for MSM , which is same as dimethyl sulfone since dimethyl sulfone is also known as methyl sulfonyl methane. The weight percent is 10% and this is within the weight percent claimed in claim 30 and this weight percent is covered by claim 31.

Accordingly it would be obvious to one of ordinary skill in the art at the time the invention was made to prepare peel compositions by using trichloroacetic acid which is taught and claimed by patent '176 and add solvent dimethyl isosorbide taught by patent '881 and add dimethyl sulfone taught by WO document with the reasonable amount of success that the dimethyl isosorbide when used as vehicle is capable of solubilizing the keratolytic agent trichloroacetic acid and the solvent being dermatologically beneficial, stable and pharmaceutically acceptable for topical formulations and adding dimethyl sulfone as the vehicle so that prolonged therapeutic effect of the active ingredient like tri fluoro acetic acid can be achieved. This is *prima facie* case of obviousness.

Response to Arguments

Applicant has not addressed this rejection.

This rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JYOTHSNA A VENKAT /
Primary Examiner, Art Unit 1619